UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE: NEW ENGLAND COMPOUNDING PHARMACY CASES LITIGATION) MDL NO. 13-02419-RWZ

BEFORE: THE HONORABLE JENNIFER C. BOAL

MOTIONS HEARING

John Joseph Moakley United States Courthouse
Courtroom No. 12
One Courthouse Way
Boston, MA 02210

August 5, 2015
3:00 p.m.

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P R O C E E D I N G S

(The following proceedings were held in open court before the Honorable Jennifer C. Boal, Magistrate Judge, United States District Court, District of Massachusetts, at the John J. Moakley United States Courthouse, One Courthouse Way, Boston, Massachusetts, on August 5, 2015.)

COURTROOM DEPUTY YORK: Today is August 5th, 2015. We're on the record in the matter of In Re: New England Compounding Pharmacy, Case No. is 13-MD-02419. Will counsel please identify themselves for the record.

MR. NOTARGIACOMO: Ed Notargiacomo from Hagens, Berman, Sobol, Shapiro for the Plaintiffs' Steering Committee.

MS. DOUGHERTY: Good afternoon, your Honor. Kim Dougherty from Janet, Jenner & Suggs on behalf of the Plaintiffs' Steering Committee.

MR. GASTEL: Good afternoon, your Honor. Ben Gastel from Branstetter, Stranch & Jennings on behalf of the Plaintiffs' Steering Committee.

MR. LEE: Good afternoon, your Honor. Andrew Lee from Janet, Jenner & Suggs on behalf of the Plaintiffs' Steering Committee.

MR. ELLIS: Good afternoon, your Honor. Rick Ellis for the plaintiffs.

MR. GROSSMAN: Good afternoon, your Honor. Steve Grossman from Montgomery McCracken Walker & Rhoads on behalf

of the Inspira defendants.

MR. WOLK: Good afternoon, your Honor. Christopher Wolk from Blumberg & Wolk on behalf of the Premier defendants.

MS. PUIG: Good afternoon, your Honor. Yvonne Puig on behalf of Saint Thomas Entities.

MR. TARDIO: Good afternoon, your Honor. Chris Tardio for the Tennessee clinic defendants.

MR. HAMPTON: Good afternoon, your Honor. Assistant Attorney General David Hampton on behalf of the Massachusetts Board of Registration of Pharmacy.

MR. KIRBY: Good afternoon, your Honor. Greg Kirby on behalf of the Box Hill defendants.

MR. CHASTAIN: Good afternoon, your Honor. Parks Chastain and Ashley Geno for Specialty Surgery and Dr. Lister.

THE COURT: Anyone else? I think we have people on the phone as well. My understanding from Mr. York is there's no one on the phone that wishes to speak, but if an issue does come, hopefully, I will remember at the end and I will ask you at that time.

I appreciate everyone's indulgence in the change of schedule. I, unfortunately, had to attend a funeral this morning and those were, obviously, outside of my control, but I appreciate everyone's flexibility in appearing here this afternoon.

Judge Zobel did ask me to remind everyone that in her

order dated July 9th of 2015, that on Page 5 of that order, it does require the parties to select 16 potential Bellwether trial cases by August 14th in light of the §157(b) briefing and until the Court orders otherwise, she would like that process to continue.

I also did want to mention on September 10th, I have a couple of moving pieces. So, I'm not sure yet whether I'm going to be able to go forward at 11:30 with the conference and I did just want to get the parties' input whether you would prefer, if I can, if I could do it the day before, whether you would rather me to do that or, if possible, to do what we did today and tag it on after Judge Zobel's hearing. I'm going to try to keep 11:30, but if I can't, does the PSC have a preference?

MR. NOTARGIACOMO: I think the PSC would prefer to tag it on like we did today.

THE COURT: All right. And the Tennessee defendants?

MS. PUIG: Same, your Honor.

THE COURT: All right. And how about on the back table?

MR. WOLK: That's fine, your Honor. Tag it on afterwards is fine.

THE COURT: All right. Well, that's what I will try to do. I think that's it for the scheduling matters, and I'm going to move on to the motion with respect to DPH.

So, would you like to have a seat at the table?

MR. GROSSMAN: Your Honor, this is Steve Grossman on behalf of the Inspira motion.

THE COURT: Yes.

MR. GROSSMAN: I have a 5:20 train.

THE COURT: Well, we can take that --

MR. GROSSMAN: Would you mind? Otherwise, I'm here the rest of the night.

THE COURT: No. I'm happy to. And since I believe the attorney for the Commonwealth of Massachusetts is local, I think that we can do that.

MR. GROSSMAN: If that's okay with the rest of the parties.

THE COURT: That's fine. And I assume that's all right with everybody else.

MS. PUIG: That's fine, your Honor.

MR. GROSSMAN: Thank you.

THE COURT: All right. And I appreciate your changing your schedule to modify -- to accommodate my schedule. All right.

So, I will hear the Inspira motion, and that was filed by Inspira.

MR. GROSSMAN: Correct, your Honor. And thank you for the opportunity to be heard today.

My intention today is not to rehash the arguments

that we have submitted and set forth in our moving papers. Instead, I thought I would address, you know, the impact of the ever-changing procedural landscape that I think has occurred and continues to occur since the time that we did file the motion.

First, however, I do want to make sure that the distinction between the cases against Premier only, the cases in which Inspira is a named defendant, that that remains a critically important distinction.

THE COURT: Why is that critical? Because we're not at the case-specific fact discovery.

MR. GROSSMAN: So, it's been our position since the beginning that, indeed, this is case specific.

THE COURT: But they're not asking for statements about the plaintiffs or things like that. It's more about policies and procedures.

MR. GROSSMAN: Right. So, our position with that -- when the Court entered the MDL order addressing common discovery, for example, it was our intention, I think most of the parties here that time, that was really directed towards the national defendants. It was directed towards the Insiders, NECC, and the affiliated defendants. I don't think the intention at that point in time was really the clinic-related defendants since it wasn't common to all cases in the MDL, which is what we set forth in our brief. Really, the

percentage of cases that we are named as a defendant is miniscule.

Now, I recognize that the landscape has changed somewhat with respect to the ability of the defendants or the co-defendants, Premier at this point, to do any discovery considering your recent order on their invoking of the Fifth Amendment, but at this point I think we've always taken the position that this is case specific. This should be handled at some point later in the process.

As I've explained in our brief, and I can certainly set forth today, really from a practical standpoint, Inspira may never really be part of the Bellwether process. It's our view at this point in time, now that no one, essentially, consented to trial in this venue -- and I understand there was argument on other reasons it should stay here. To the extent that that does not occur, all these cases are going to be -- at least the New Jersey cases, are going to be remanded sometime -- or sent back sometime in February of 2016 for case-specific discovery.

Through that Bellwether process, it's our position it's very unlikely at any time that the plaintiffs are going to choose -- or that a Bellwether trial is going to include a case that involves Inspira. Those cases that will proceed will proceed against Premier only, and because of that -- I mean, that's going to be a representative case for a

Bellwether trial. Because of that, we don't see why we need to partake in discovery as a settling defendant, to pay a significant sum to resolve the claims against us at this point in time. We're not saying it can't happen. We're saying that there's really no urgency, and we explain this to the Premier defendants. The discovery needs to take place now.

To the extent that Inspira is ever part of a trial, a Bellwether trial process, which we don't believe will ever happen -- for example, if Premier goes to trial and wins its cases at trial, then, really, the value of the remaining cases becomes less significant. We would expect the remaining cases to settle.

To the extent that Premier loses at trial, the value of those 35 cases becomes significantly more and it's likely -- given what we understand their insurance to be, that it's likely they'll be well above their policy limits and, again, those cases are going to settle, including the 21 cases against Inspira.

So, from our perspective, we're going down a path of discovery that's never going to be necessary, and why the distinction is important is because in those 35 cases that involve Premier only, it's very clear that Inspira had nothing to do with the way in which Premier vetted, ordered, administered the NECC MPA to its patients by its doctors at its facilities. There's nothing from Inspira that's going to

add or change that. So, they're not entitled, in our view, to the discovery of those 35 cases, which impacts, again, as I just mentioned, how we see the Bellwether process unfolding.

And so, for those reasons -- and I won't belabor some of the other points -- we don't think at this time that Inspira should be subject to the depositions that they are seeking. At some point in the future, to the extent that that discovery becomes necessary or critical in a case that would involve Inspira, certainly, as I explained to both Chris and his partner, Jay, we would work that out. That's what we anticipated we would do from the date that we spoke and tried to resolve this. Instead, we're here hoping that the Court will hear our plight and certainly just wait for the appropriate time.

THE COURT: And I believe you made an argument about privileged materials. Is that limited to the materials submitted during the settlement process or --

MR. GROSSMAN: So, it would be -- we responded primarily in our reply brief to bolster the position that the mediation materials, which can be the only thing that they're asking for with respect to that particular category, that they're not entitled to that information.

Rule 408, the cases that we cited -- I mean, to allow them -- to the extent that even materials were exchanged in the process -- I'm not going to say one way or the other if

they have a mediation privilege or an agreement not to disclose that. To the extent that even occurs, they're not entitled to that. They can find out the underlying facts in any other reasonable way other than seeking what settlement negotiations and discussions took place over almost a year and a half of negotiations.

THE COURT: Thank you.

MR. GROSSMAN: Thank you, your Honor.

MR. WOLK: Thank you, your Honor.

I'm having difficulty understanding the objections -- I've read the papers and I've heard Mr. Grossman's argument -- to the point that this is case-specific discovery. It is not. This is common to 100 percent of Premier's cases.

There is evidence in this case through the deposition testimony of Michelle Cassidy, which was attached to our motion -- to Mr. Grossman's motion, actually, regarding her and Premier's interaction with Inspira in the 2009-2010 timeframe when they were to open their surgery center.

Unequivocally, Ms. Cassidy testified that there was a recommendation that -- she used that word -- by Inspira to use New England Compounding as the source for their preserving free MPA. She testified unequivocally that she had a conversation with the pharmacy at Inspira and Dr. Metros who was an Inspira employee at the time, who was not only the chief of anesthesia, but is also a pharmacist, and this

conversation occurred in the process of investigating and determining whether -- who to use to fill these orders and whether to use New England Compounding. We're entitled to know what the substance of those conversations were from Inspira's perspective between the individuals that she spoke with, but to a different point besides just Ms. Cassidy's testimony about her interactions with Inspira, which make all of the requests we've made to date highly relevant to our defenses in this case, is that 21 of the 35 cases pending currently against Premier and its doctors occurred at Inspira, where they ordered the medication.

Now, Mr. Grossman tries to draw the distinction that 21 out of 35 isn't enough cases to make it that common discovery. So that it should be distinguished in some way so that we can wait until later when it becomes appropriate during case-specific discovery.

I submit to your Honor that it makes no difference whether there was one case, whether there were 35 cases where Inspira was a defendant. The conversations -- the interaction that Ms. Cassidy and Premier had with Inspira is relevant to our defenses in this case, as I've pointed out in my papers, and I won't go through all of the particular reasons why it's relevant, but to hit some of the high notes, it's relevant towards standard of care and the proof of what the standard of care was at the time.

Most importantly, it's relevant to show what due diligence we did, what Premier did, and the basis upon which we relied on Inspira's recommendations coming straight from Inspira's knowledge, and that's why we need the depositions and that's why they're relevant.

Mr. Grossman has the burden here. He has the burden in this motion for protective order to show that this information should somehow not be sought, and I don't think Mr. Grossman has met his burden in that capacity.

Rule 26 should be read broadly, as we have pointed out in our papers, and even if it was not to be read broadly, your Honor, it was to be given the strictest interpretation in this case. We feel that the information Inspira has about New England Compounding and, most importantly, about its interactions with Premier, my client, a defendant in this case, is highly relevant.

THE COURT: Is Premier in all of the New Jersey cases?

MR. WOLK: Yes. In this case, just to address some of the other points that were made, there was a comment made that it's just not practical to do it now or have the discovery done now.

Well, I submit to your Honor that it's not practical to wait. We're under a deadline in this case, one of which has already passed. That is, the discovery against the

settling defendants, which one could argue that Inspira is part of it because they have, in fact, settled. The other is a common discovery deadline of November 15. I'm not so sure that we can wait much longer.

Your Honor was correct. I did not see in the papers an assertion of any privileged material in this case aside from what may have been inferred from the arguments about the information from the settlement. We did ask for that.

Mr. Grossman admits in his own papers in his reply brief that the facts underlying the settlement in this case is discoverable, is relevant. I'm not exactly sure how it was phrased in the papers, but concedes that that would be the only information we would be entitled to. Well, certainly, that is the information we're looking for.

So, if Inspira disclosed to the PSC during their negotiations some information that they had about NECC, we would want to know that. If they disclosed and handed over information about their contacts and their relationship with Premier, we would want to know that and would be entitled to it.

Another issue that is impacted here is our comparative fault defenses and we're not going to shy away from that. In these cases where Inspira is a defendant, we can show this jury that it wasn't Premier's responsibility to order this medication.

And to the point that we need to wait until the Bellwether process, I don't know how we can determine now whether or not an Inspira case -- and I use that term -- a case where Inspira was a defendant will be chosen as a Bellwether case or not. Certainly, if they're not going to be chosen as Bellwether cases, I'm prepared to take a dismissal on those cases right now from my clients. Why would we be here otherwise if they weren't part of the potential cases that could be chosen.

THE COURT: If I read your discovery requests correctly, there was no date limitation. Is there a permanent date limitation that's been used in discovery requests?

MR. WOLK: I did see that in there, and that -- I think we have -- at some point in some discovery that's been going back and forth between the plaintiffs and the defendants, we have agreed on a date range and I can clarify that.

THE COURT: Do the plaintiffs know what the date range is for discovery?

MS. DOUGHERTY: It's unlimited in these discovery requests.

MR. GASTEL: Your Honor, I believe the plaintiffs have been using for the vast majority of our requests -- and if I recall correctly, it's been a while since I reviewed those -- we've been using the period with regard to sort of

NECC-related materials from January 1, 2011 until, I believe, the end of calendar year 2012.

MR. WOLK: Now that I'm reminded of that timeline, that wouldn't work for our discovery requests because we're dealing with information that occurred back in 2009, when we were formed, but -- when Premier was formed, but, also, I would request that we can discuss and have disclosed by Inspira information beginning with their relationship with NECC going forward, because I think that's what's relevant here.

THE COURT: All right. Anything else, Mr. Grossman?

MR. GROSSMAN: Let me just briefly respond to, I think, generally all the comments that Premier has made here today.

THE COURT: And, actually, Mr. Grossman, I'll give you the last word. Does the PSC -- I didn't have any briefing from you. Are you taking a position on --

MR. GASTEL: No, we have no position on this, your Honor.

THE COURT: All right. Is there anyone on the phone that wants to speak to this motion?

(No response.)

THE COURT: All right. Mr. Grossman.

MR. GROSSMAN: So, real quickly, Premier argues this is necessary for the standard of care and due diligence, but

all of these arguments are premised, essentially, on Premier's fiction of what their own witness testified about.

All she testified to was that she asked this recommendation -- all this is, is that she asked Inspira's pharmacy for contact information. It's not a recommendation. I don't know what "recommendation" means, but to Ms. Cassidy, their own witness, they asked for contact information, the name of the manufacturer, which she knew, and the contact information, which she then took upon herself to move forward and contact because Premier's doctors had familiarity with the product. They used it for years at Inspira and they were to continue to use it, regardless of what we would say, but we didn't say anything and their witness said that. All they got was contact information.

So, this whole position that they're taking of relevancy in 100 percent of the cases is premised on fiction that's not on the record. And I'll end with that, your Honor. Thank you for indulging me.

MR. WOLK: Your Honor, may I just briefly --

THE COURT: Briefly.

MR. WOLK: Very briefly, I will.

Perhaps maybe Ms. Cassidy is mistaken. I don't know. How do we know unless we get the deposition? It's the risk we take every time we swear someone in.

And just one more point, your Honor. Inspira set up

a clinic to treat these patients when the outbreak came up. They treated each and every one of the patients that were injected at Premier and also at Inspira, which is another area of information I did not include in the deposition notice, but I can amend it or I'll move to amend it.

And, finally, your Honor, I'll end with this. There was comment in the brief papers about the order, the mediation order barring or staying discovery against the defendants, and I would submit to your Honor that we would request that that order be lifted.

THE COURT: All right. Thank you.

Mr. Grossman, I think you have plenty of time to make your train and you're welcome to leave if you would like to do so.

MR. GROSSMAN: Thank you, your Honor. I appreciate it.

THE COURT: All right. Should we go to the DPH motion or does someone want to have something else heard first?

(No response.)

THE COURT: All right. So, we'll do go to the DPH motion.

MR. HAMPTON: Thank you, your Honor. Again, I am David Hampton, Assistant Attorney General on behalf of the Massachusetts Board of Registration of Pharmacy, and to the extent there's overlap, the Department of Public Health.

We're here on the board's motion for protective order.

As your Honor is no doubt aware, we are moving for a protective order to the same extent and for the same reasons as the Food and Drug Administration recently moved for a protective order against the Rule 30(b)(6) testimony as requested by the Tennessee --

THE COURT: Isn't the DPH in a different position? It is not part of the criminal investigative team. It certainly was not one of the listed agencies in the U.S. Attorney's Office's press release as participating in the criminal investigation as distinct from the FDA.

MR. HAMPTON: To the extent that you say, it is in a different posture, but, as I understand it, witnesses who were inspectors for the board and for DPH who had firsthand information about --

THE COURT: But how is that different? I assume some of the plaintiffs will be witnesses.

MR. HAMPTON: Because, as I understand it, it's going to be a critical part of the case in chief as presented by the Department of Justice in its criminal prosecution.

To some extent we have to take the Department of Justice at its word. I assume that the seven-page affidavit from the U.S. Attorney is not sworn out idly in support of our motion for a protective order, and perhaps by explaining kind of the evolution of this motion for a protective order, your

Honor can better appreciate the posture that we are in.

We first received the subpoena from the Tennessee defendants in March and entered negotiations and discussions with the Tennessee defendants over the scope of Rule 30(b)(6) testimony and over the scope of our document production in response to the duces tecum.

As we were contemplating a particular production, I reached out to the Department of Justice and said, I understand there is a criminal prosecution proceeding. We intend to make a document production. Do you have any concerns about that and its potential prejudicial effect on the criminal prosecution? To which the response was no. However, has Rule 30(b)(6) testimony been requested from the board? We're aware that such testimony had been requested from the FDA in response to a very similar subpoena.

I informed them that it had. And they said, Well, we do have grave concerns about the Rule 30(b)(6) testimony moving forward and, therefore, we would ask you to raise a motion for protective order to protect the same kind of considerations, the same considerations that are at issue in the FDA's motion; namely, the fear of pretrial publicity, the requirement that one or more AUSA's would have to essentially ride herd on the civil -- on this MDL, participate in the preparation of witnesses and otherwise participate in this case to make sure that it's not having undue prejudicial

effect on the criminal action and unnecessarily prematurely require the Department of Justice to formulate and then disclose its case in chief before such time as is appropriate, and for those reasons --

THE COURT: So, do you have -- are there particular concerns in the 30(b)(6) of any of the topics more than others or are you just making a blanket assertion?

MR. HAMPTON: We are making a blanket assertion because, good lawyers that they are, the topics that --

THE COURT: Well, good lawyers would probably make alternative arguments.

MR. HAMPTON: It's a very comprehensive list of topics.

THE COURT: Right, but are there ones on here that are more concern than others?

MR. HAMPTON: Ten of the topics are, although verbatim counterparts of those that are -- were the subject of the FDA subpoena for which this Court previously allowed the--

THE COURT: Right. I'm asking from the DPH's perspective.

MR. HAMPTON: Yes. From DPH's perspective, for our own sakes, our concerns are only coextensive with those of the Department of Justice.

My understanding is there's particular sensitivity around 2012, particularly September 2012 and afterward, but

because our concerns are really just those of the DOJ, I'm not in a particularly good position to speculate as to which ones would give more --

THE COURT: So, you've been put in a difficult position.

MR. HAMPTON: To some extent, your Honor.

I'd like to clarify that, just like the FDA's own motion, this is not consider -- concern the document production that's been requested.

THE COURT: Had the documents been produced?

MR. HAMPTON: The 15,000 pages of documents are currently at our vendor and are -- will be available for pickup by the plaintiffs' counsel as soon as they pay their share. We've entered into a cost-sharing arrangement. What I understand to be a little less than a thousand documents, the remainder of our production, will be finalized within two weeks and will then be available for --

THE COURT: I believe it was the Tennessee defendants that wanted the documents.

MR. HAMPTON: Oh, I apologize. The Tennessee defendants.

THE COURT: So, they don't have them yet, but they're going to be available in the next week or so?

MR. HAMPTON: All will be available by the end of next week. I believe the vast majority will be available

tomorrow.

THE COURT: All right.

MR. HAMPTON: And unless other issues arise in the course of these arguments, we're happy to rest on our motion, on the arguments raised in the FDA's motion and the reasoning in this Court's allowance of the FDA's motion.

THE COURT: All right. Yes, Mr. Tardio.

MR. TARDIO: Thank you, your Honor.

The Court's reasoning in denying us the opportunity to depose the FDA, as I read the order, was because the deposition of the FDA would directly impact the FDA's investigation and prosecution of the criminal Insiders.

I don't think there's really anything unclear about this Court's order on that point, and the Massachusetts Board of Pharmacy is not in that position, and the Court, I think in questions earlier, obviously recognizes that distinction, but that is a key, key distinction, and I think that distinction permeates the papers filed by the Massachusetts Board of Pharmacy.

It seems to me that if anybody should be moving for a protective order on this deposition notice, it should be the U.S. Attorney. Again, the Massachusetts Board of Pharmacy has not demonstrated any burden on it that I can see in the papers or have heard here today in producing a witness for a deposition. It sounds to me like the Massachusetts Board of

Pharmacy is simply reciting what they have been told by the U.S. Attorney. The U.S. Attorney can move for a protective order on this motion. The papers filed by the Massachusetts Board of Pharmacy, with all due respect to the board, do not come anywhere close to meeting the heavy burden that is required to grant a blanket protective order like they have asked for.

I can address any specific questions, but this is clearly a discretionary matter, and the caselaw is clear that this is not something that should be granted without sufficient evidence in the record of a heavy burden. It's their burden. They haven't met it. The deposition notice should stand and the Massachusetts Board of Pharmacy should be required to comply. Thank you.

THE COURT: All right. Thank you.

I'm going to take it under advisement. You're welcome to stay or you're welcome to leave, whatever you want.

MR. HAMPTON: Thank you, your Honor.

MR. LEE: Your Honor?

THE COURT: Yes.

MR. LEE: The PSC had actually submitted a response.

THE COURT: Yes. Did you want to speak to it?

MR. LEE: Yes, very briefly, just for the record.

We had made arguments that our -- actually, not related to the criminal proceeding, but were for other

considerations, some that are related to the choice of law issues that are implicated in some discovery requests.

However, considering the recent order -- I'm not going to delve too far into that. However, I would like to state that the PSC still maintains that the 16,000 documents that the board is going to be producing within a week are sufficient for any discovery required by the Tennessee clinic defendants if there is comparative fault allowed or even if there isn't.

THE COURT: Thank you. All right.

So, the next motion is the PSC's motion to quash the subpoena to Dr. Austin.

MS. DOUGHERTY: Yes, your Honor. Thank you. Once again, Kim Dougherty on behalf of the Plaintiffs' Steering Committee.

The Plaintiffs' Steering Committee has moved to quash the deposition subpoena of Dr. Austin for primarily three reasons. The first being that to allow that deposition would be directly in violation of Federal Rules of Civil Procedure Rule 26(4)(d), which protects discovery of non-testifying consulting experts.

The second is that the information sought through this deposition has already been provided to the defendants by the PSC and is also available through other means and would make this entirely duplicative, including the means of the

deposition that was just recently ordered by your Honor last week of Steve Higgins, and I'll get to more detail on why he is the more appropriate person to gather the discovery that they are seeking.

And, third, it's also premature even if the Court were to decide to allow expert depositions. The disclosure of experts under the current schedule is not for several months from now and the expert depositions are months after that, but we can tell you today that we are not planning to put forth or disclose Dr. Austin. The Plaintiffs' Steering Committee will not be doing so in the Tennessee cases or likely ever.

The defendants seek primarily three areas of information. The first is pictures from the inspection. Over 4,000 photographs have already been produced to the Tennessee defendants, along with four days of video footage, and those were already produced in our initial disclosures to the defendant. So, we believe that argument there is moot.

Dr. Austin actually did not take any photographs, it's our understanding. It was another consulting expert that took over 4,000 photos which were provided to the defendants.

They were also provided all the testing results. We provided them, I believe, six or seven different categories of testing results. All of the test results were also produced with our initial disclosures and, again, Dr. Austin did not perform any testing of any kind. He didn't do any sampling of

any kind. So, he has absolutely no information to provide with respect to testing or test results which have already been provided. So, we believe that issue is also moot.

What is the current issue, probably most likely, before the Court that you're interested in hearing about are the observations and the requests to seek the observations of Dr. Austin, and we believe, as I previously stated, that Rule 26(4)(d) is clear. As the Court is well aware, the Rule states that ordinarily a party may not, by interrogatories or a deposition, discover facts known or opinions held by an expert who has been retained or specifically employed by another party in anticipation of litigation or to prepare for trial and who is not expected to be called as a witness at trial.

Dr. Austin falls precisely within this rule. He has not been disclosed as a testifying expert by the Plaintiffs' Steering Committee and he will not be disclosed by the steering committee in any cases against the Tennessee defendants or ever, likely.

He's only served in a limited capacity as a consultant. The fact that he filed an affidavit in response to a summary judgment motion involving a small number of Indiana clinics involving an entirely different defendant where Tennessee defendants were not named does not suddenly do away with the rules.

THE COURT: And this may have been a typographical error, but you know in the caption there's a sub-heading and it says what case the documents are filed in, and for Dr. Austin's declaration it says, "This document relates to all actions."

MR. GASTEL: Yes. I think that that's probably a hold-over caption. I think if you look at the PSC's response to the actual motion, we triggered that over to the original Liberty motion for summary judgment, which actually lists the Indiana cases in which it applied. So, that's probably a drafting error on behalf of somebody who went into and just grabbed the previous case caption and wasn't aware that Liberty simply filed that motion on very limited Indiana cases.

MS. DOUGHERTY: So, yes, your Honor, I believe you're right that it was a typographical error.

I would like to point out with respect to that briefing related to the Indiana clinics, the Saint Thomas Entities specifically stated as non-parties to those proceedings the Saint Thomas Entities lack standing to participate in that briefing.

So, they clearly took the position when it was going on at that time that they had no interest whatsoever in those cases, no interest in the briefing that was going on and that they had absolutely no standing in order to respond to any of

that briefing, and that does not change today.

So, there's caselaw on point as well, your Honor, that supports the PSC's position, and we hadn't cited this in any of our briefing, but we're happy to provide the Court with a copy of it and supplement if you would like.

There's a case called *In Re: Brussels Lambert vs. Chase Manhattan Bank*, 175 F.R.D. 34, Southern District of New York, 1997. In that case the plaintiff sued two defendants. An expert was identified in one of the cases against the EY defendants, but not in the other cases that were against the CLS defendants. The cases were consolidated, like here, for pretrial proceedings, but not for trial.

And so, just like in that case, the Tennessee defendants here are like the CLS defendants there, where they sought to depose the expert that was identified by the plaintiffs in the EY case, and even though the plaintiffs had not identified the experts in the CLS case, the Court ruled and held, "Not all parties are entitled to depose a given witness simply because the parties in one case demonstrate that they are entitled to depose that witness. The parties in the CLS case must independently demonstrate their entitlement to depose a witness."

The Court went on to allow the deposition in the EY case, but in ruling in the CLS matter, the Court held, "The CLS parties have no interest in preparing to cross-examine

Anderson, the testifying expert, at trial. Accordingly, there is no basis to permit CLS parties the right to depose Anderson as a testifying witness. Thus, Anderson qualifies as a non-testifying expert for the purpose of protecting under the Rule 26(b)(4)(D).

THE COURT: So, the wrinkle here is, obviously, the December 2012 inspection was ordered under sort of unusual circumstances.

MS. DOUGHERTY: Yep.

THE COURT: And as part of that order -- and I think this is what you were telling me the PSC has complied with, that they had to share all the results with the defendants.

The evidence that was gathered there and Dr. Austin's observations in some ways now are unique. He's almost a fact witness in many ways. So that's what strikes me as a little bit different from the cases that typically rely on 26(b)(4)(D).

MS. DOUGHERTY: Yes, your Honor. He may be a fact witness, but so are many people, and the fact witness that is the most appropriate to get the observations that the defendants are looking for is the fact witness you just allowed last week, Steve Higgins. Mr. Higgins managed the entire facility. He was there the four days of that inspection. He was there again during the Tennessee inspection. He's been there throughout the entire time

managing the facility and the property. He's the person to be asking the questions about the observations. He has the most information that's available.

THE COURT: And when is Mr. Higgins' deposition -- I mean, he's -- his lawyer had said he would assert the Fifth, but --

MS. PUIG: It's not set yet, your Honor.

MS. DOUGHERTY: We also have provided the four-day inspection, which provides the information that was -- could be directly gathered, because these experts were -- literally had video cameras over their shoulders. So, four days of the entire day-long is video footage showing exactly what was observed by Dr. Austin. And so, too, were all of the photographs that were available to him.

And we also have agreed in terms of authentication and whether that's a potential issue, that we will stipulate and we'll work out some language to stipulate to the authentication of both the photographs and the video footage. So that shouldn't be an issue when their experts would like to look at those and rely upon those at trial.

None of the cases that the defendants have cited show that they are entitled to Dr. Austin's testimony. The two cases that they cited, *Morning Ware* and *Morley*, and, frankly, all the other cases, are entirely distinguishable because, unlike in those cases, the PSC has never filed a sworn

affidavit of Dr. Austin in cases involving the Tennessee defendants. In every single case that they've cited to, the expert had filed a sworn affidavit previously. And so, we think that's entirely different here, and even Tennessee has admitted and admitted at the time, that they lack standing to brief in those matters.

The other case that has been cited to and an issue that has been raised by the Tennessee defendants is some alleged alteration of evidence and they spent a lot of time quoting my argument here in front of you and in front of Judge Saylor in the past with respect to the evidence, but what they don't note is that at that time when I was making those arguments to the Court, no preservation orders were in place.

We had a very grave concern that the evidence could change or be altered because no preservation order was in place. And so, quickly after a preservation order was put into place, which has been respected completely by the trustee -- as we heard just even today, the trustee and Ameridose were in front of Judge Zobel asking whether they could destroy 100 pallets of paper from Ameridose. Every time they've sought to do anything to alter the facility or to change anything in any way, and including Ameridose's facility, they've come to this Court and said, Please, may I, your Honor, do this or do that.

So, what the Tennessee defendants saw when they saw

the inspection in 2014 was nothing different than Dr. Austin observed himself. There has been no change or alteration to the facility, and I think the trustee would also support that position. So that does not entitle them to deposition testimony from a consulting expert who's not the only person available and not the only source of evidence.

Clearly, what we're looking at, what we're really seeing here is that they don't want facts. They don't want observations. They want opinions, and that is not what they're entitled to.

So, your Honor, we also looked at their case *McDonald Sprayed Roofing*. This is a case that they cited to support that the expert was the only one able to provide the testimony.

Well, in that case there had been significant alterations to the roof between the time that the defendant expert observed it and the time that the plaintiff's expert observed it. The entire roof had actually been covered and replaced with another roof, which made it impractical for the plaintiff to obtain the facts that they needed at that time.

We don't have that scenario here, your Honor. We have a situation where nothing has changed. Nothing has been altered, and the defendants have been given the opportunity to get the evidence and the inspection that they need, along with 4,000 photos, four days of video, now other depositions of

other key potential witnesses, and they've got all the evidence they need available to them, and Mr. -- Dr. Austin's testimony should be quashed, any deposition. Thank you.

THE COURT: Thank you.

MS. PUIG: Your Honor, Yvonne Puig for the Saint Thomas Entities. Thank you for the Court's careful attention to detail and picking up on the notation as to all actions with respect to Dr. Austin's declaration.

The Court is right in suggesting that Dr. Austin is unique among any one in this case. He is unique in that the PSC will have you believe he's not an expert. He's only a consultant. If he's a consultant, we don't satisfy Federal Rule 26(b)(4)'s exceptional circumstance exception or standard, and we do, and I'll take each of those arguments in turn.

Dr. Austin's declaration is filed as Exhibit A to Document No. 2100, our opposition to the motion to quash. The depth and breadth of his observations is nothing less than breathtaking. It is stunning. He is a fact witness. And for the PSC to argue, go get Mr. Higgins who worked there, it will not be the same.

He had extraordinary access. He's one of the only people we've heard who walked on the catwalk above the grid system that held 77 HEPA filters, some of which were not even connected, some of which you could see light through, some of

which you could put a pencil through, and it was Dr. Austin's belief that it was this area directly above the clean room where the compounding occurred that was a proximate cause of the contamination. While he didn't give it a sole cause, he did say in his declaration it was a proximate cause of the contamination.

They opened the door. By filing the declaration, they were able to secure a large settlement from Liberty, and this Court denied summary judgment, possibly in large measure, as a result of Dr. Austin's declaration.

On the issue of whether he's an expert, we think that they did put him forward as an expert. They filed his declaration. They opened the door. If he's only a consultant, we clearly meet the exceptional standard. We clearly believe he's virtually a sole source, and to argue go get Mr. Higgins or go get somebody who did the walk-through -- the walk-through was attended by officials from federal agencies and the PSC. We can't turn anybody into a fact witness on the PSC or their lawyers. We can't turn federal agents into witnesses. We can't even get witnesses now with knowledge of relevant facts, including the Insiders. So, clearly, it is not practical, as the rule anticipates. So, we are --

THE COURT: So, you're seeking both his factual observations and also his expert opinion?

MS. PUIG: To the extent he has any expert opinions, but what is key to us are his factual observations, what he saw over those days, what he saw from the catwalk, what he saw on the clean room walls, what he saw regarding Liberty's defective design, and that's key to us.

The next argument is he's only a consultant and you don't satisfy the exceptional standard. We think we do. We think that's amply demonstrated, if by no other document, his own declaration.

Then they argue you've already been provided this information. You have a videotape. You know, you can go out and hire an expert and they can express opinions on the videotape.

In this instance, Dr. Austin and his father saw it in December 2012. I won't recite what is contained in our brief or what Ms. Dougherty. Let's go to what Frederick Fern said in this courtroom years later in describing why we shouldn't have access for a walk-through in the summer of 2014. This is contained at Page 9 of our opposition:

"Going in there and looking at the equipment, Judge, there is nothing in the same condition as it was in October of 2012. There's no air conditioning. There's no vent." And he goes on and on.

So, it's disingenuous to argue it was critically important to the PSC to get in there quickly in the fall of

2012, and then by the time we saw it in a three-hour walk-through last summer, that nothing had changed. I think the Court can see clearly through that argument.

With respect to having an expert rely solely on the video, you can imagine that cross-examination, that we're expressing opinions solely on the video and not the factual observations of a trained expert, one of the premiere experts in clean room design, Dr. Austin and his father, Dr. Austin, in December of 2012.

With respect to we've been provided with every single thing that's possible, we don't know that until we depose Dr. Austin to test the authenticity of that statement.

With respect to the sweeping request for protective order, my arguments are almost like Mr. Tardio's. They have failed to satisfy that burden. It's a steep burden. They haven't satisfied it. What's the serious injury? What's the harm? What's the burden?

With respect to the challenge that it is premature and I will have my time, if they were to name Dr. Austin by October 25th and I would have to depose him by December 15th -- that's what I thought you were going to hear today, your Honor. Today we hear they're not going to name him as an expert. So, my chance, even on the prematurity argument, has just sailed away by the admission in the courtroom today.

I need his testimony now. That's why we requested it

when we did, and I certainly would need his testimony either at or near the time or before Mr. Higgins to put that into context. We have had to take these depositions without these observations and it has been an uphill climb.

So, your Honor, I would ask that under Rule -- Federal Rule 26(b)(4), that if you find him to be an expert, you will allow us to depose him right away. If you find that he's not, he's merely a consultant, that you find that we have satisfied our burden to prove that it is an exceptional circumstance.

Last, but not least, that it is not premature and that I must wait my turn, and now I hear today he will not be identified.

Last, but not least, they have wholly failed to satisfy their burden for a protective order.

I want the Court to be aware, and I have outlined it in my briefing, that we offered to pay the reasonable expenses of Dr. Austin. And so, this will not be an expense to the PSC other than for them to show up and present him, your Honor. It is not an unreasonable burden. It is manifestly fair, and any burden is outweighed by our demonstrated necessity to have this witness. Thank you, your Honor.

THE COURT: And I understand the comparative fault arguments, but is Liberty -- was Liberty a defendant in any case in which the Saint Thomas Entities were a defendant?

MS. PUIG: I don't think they were in the case with the Tennessee defendants. With respect to the Indiana defendants -- and, your Honor, I would ask the Court to take notice of pleading No. 2112, which is the joinder of the anonymous clinic defendants, the Indiana defendants, and our joinder exists, and that we represent some of those anonymous clinics, which are required to be identified as anonymous under Indiana medical malpractice statute. Thank you, your Honor.

THE COURT: Anything further from the PSC?

MS. DOUGHERTY: Just a few points of clarification, your Honor.

Attorney Fern made these same exact representations when the Plaintiffs' Steering Committee was seeking to have the inspection of the facility back in November of 2012.

THE COURT: I well remember the arguments.

MS. DOUGHERTY: Okay. So, that's nothing new. That's just a rehash of what was already sent to us.

So, with respect to the arguments about the air conditioning being off, clearly that's not going to affect the design of the clean room, which is what Dr. Austin was observing. The Tennessee experts have gone there themselves. They have looked at the facility themselves. If they want to seek to get on top of that catwalk, the Plaintiffs' Steering Committee is not going to object to them seeking to go and

observe the top of the catwalk, if that's what they're looking for. They've got their own experts who can take a look at it. They don't need to try -- to come and violate Rule 26 where they have absolutely no standing and seek that sort of information from a consulting expert who is not testifying.

And to question our good-faith representations with respect to what we've produced in terms of documentation, that's not sufficient to allow this deposition. Dr. Austin is not going to have the answers to those sort of questions.

So, we just ask, your Honor, that under these circumstances, where all of this vast other information is available, that you again not allow this deposition to move forward. Thank you.

THE COURT: Thank you. Does anyone have anything else?

(No response.)

THE COURT: Okay. Does anyone have anything on the phone?

(No response.)

THE COURT: All right. I will see you all in September.

MS. DOUGHERTY: Thank you, your Honor.

COURTROOM DEPUTY CLERK YORK: All rise. This Court is in recess.

(Adjourned, 4:20 p.m.)

C E R T I F I C A T E

I, Catherine A. Handel, Official Court Reporter of the United States District Court, do hereby certify that the foregoing transcript, from Page 1 to Page 42, constitutes to the best of my skill and ability a true and accurate transcription of my stenotype notes taken in the matter of No. 13-md-2419-RWZ, In Re: New England Compounding Pharmacy, Inc., Products Liability Litigation.

August 9, 2015
Date

/s/Catherine A. Handel
Catherine A. Handel RPR-CM, CRR